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APPLICATION NO. 09/373,585	FILING DATE 08/15/99	FIRST NAMED INVENTOR OGURA	ATTORNEY DOCKET NO. 055432
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EXAMINER LU, F

ART UNIT 1655	PAPER NUMBER 5
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DATE MAILED: 08/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/373,585

Applicant(s)
Ogura

Examiner
Frank Lu

Group Art Unit
1655



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-19 is/are pending in the application.

Of the above, claim(s) 4, 5, and 8-13 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 6, 7, and 14-19 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-19 are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1655

DETAILED ACTION

Location of Application

1. The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1655.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-3, 6, 7, and 14-19, drawn to a test piece for use in biological analysis of a sample (claims 1-3), apparatus for manufacturing a test piece for use in biological analysis (claims 6 and 7), and a system for reading a test piece (claims 14-19), all classified in class 435, subclass 287.2.
 - II. Claims 4 and 5, drawn to a method of manufacturing a test piece for use in biological analysis, classified in class 435, subclass 287.2.
 - III. Claims 8-13, drawn to a method of reading a test piece, classified in class 435, subclass 288.7.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be

Art Unit: 1655

made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be used to make other and materially different product such as microchip with cDNAs from different species.

Groups I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with another materially different product such as microchip with cDNAs from different species.

Groups II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions .

Groups II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are directed to different methods comprised of different method steps and result in different end products.

Art Unit: 1655

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Darryl Mexic on July 25, 2000 a provisional election was made with traverse to prosecute the invention of Group 1, claims 1-3, 6, 7, and 14-19. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4, 5, and 8-13 have been withdrawn from further consideration by the examiner, 37 CAR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The term "second direction" in claim 5 is a relative term which renders the claim indefinite. The term "second direction" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Note that claim 7 is dependent on claim 6.

Art Unit: 1655

Claim Rejections - 35 USC § 102/103

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Stephens *et al.*, (J. Biol. Chem. 266, 21839-21845, November 15, 1991).

Stephens *et al.* teach transcriptional repression of the GLUT4 and C/EBP genes in 3T3-L1 adipocytes by tumor necrosis factor-alpha. As shown in Figure 5 (page 21843), *in vitro* transcribed RNAs from nucleic treated from control and TNF were used to hybridize with different cDNAs immobilized on nylon membranes. Note that there are four strip-like substrates in this assay. This prior art meets the limitations of the claims.

Art Unit: 1655

9. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klebe (Exp. Cell Res. 179, 362-373, December 1988) in view of Proudnikov *et al.*, (Anal. Biochem. 259, 34-41, May 1998)

Klebe teach cytoscribing. During the process of preparing substrata, a 200 µg/ml fibronectin solution was injected into the ink well of an ink jet cartridge (page 365, Figures 1 and 2). The word "fibronectin" was spelled out in fibronectin on a flexible plastic film which could be rolled into the carriage of a printer (page 363, 7 and 8 paragraphs). The statements above cover the most part of claim 6.

Kelbe does not disclose cutting substrate into a plurality of strips.

Proudnikov *et al.* teach immobilization of DNA in polyacrylamide gel for the manufacture of DNA and DNA-oligonucleotide microchips. Note that single and double-stranded DNA of 40 to 972 nucleotides or base pairs were immobilized on the gel pads to manufacture a DNA microchip.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have loaded different specific binding agents onto the sheet-like substrate as suggested by Klebe, cut the sheet-like substrate into strip-like pieces and manufactured the strip-like pieces into a microchip or an array. The papers from Kelbe would have motivated one having ordinary skill in the art to load different cDNAs onto the sheet-like substrate since fibronectin has been shown to be loaded onto the sheet-like substrate, while Proudnikov *et al.* would have motivated one having ordinary skill in the art to cut the sheet-like substrate immobilized with

Art Unit: 1655

different specific binding agents into strip-like pieces in order to manufacture the strip-like pieces into a microchip or an array. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to combine these prior arts together because all of these prior arts are well known and are easy to use.

10. Claims 14-19 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stern *et al.*, (US Patent 5,631,734, filed on February 10, 1994).

Stern *et al.* teach method and apparatus for detection of fluorescently labeled materials. Figure 1a schematically illustrated a device used to detect fluorescently labeled targets on a substrate. Substrate 230 comprises a number of presynthesized probes on its surface 231. The substrate on which the sequences were formed might be composed from a wide range of material, either biological, nonbiological, organic, inorganic, or a combination of any of these, existing as particles, strands, precipitates, gels, sheets, tubing, spheres, containers, capillaries, pads, slices, films, plates, slides, etc. The substrate might have any convenient shape, such as a disc, square, sphere, circle, etc. The substrate was preferably flat but may take on a variety of alternative surface configurations. For example, the substrate might contain raised or depressed regions on which a sample was located. The substrate and its surface preferably formed a rigid support on which the sample could be formed. The substrate and its surface were also chosen to provide appropriate light-absorbing characteristics (column 3, last paragraph). A light source 100 generated a beam of light to excite the fluorescein labeled targets in the flow cell. The light source

Art Unit: 1655

might be a argon laser that generated a beam having a wavelength of about 488 nm, which in some embodiments might be a model 2017 or model 161C manufactured by Spectra-Physics (column 5, fourth paragraph). In response to the excitation light, fluorescein labeled targets in the flow cell fluoresce light had a wavelength greater than about 520 nm. The fluorescence would be collected by the microscope objective 140 and passed to optical lens 130. In practice, light collected by microscope objective contained both fluorescence emitted by the fluorescein and 488 nm laser light reflected from the surface 231 (column 6, fifth paragraph). Figure 1c illustrated an alternative embodiment of the fluorescence detection device which is similar to the embodiment shown in Figure 1a. Two color detection were required when two different types of targets, each labeled with a different dye, were exposed to a substrate synthesized with probes. In some embodiments, fluorescein and rhodamine dyes might be used to label two different types of targets respectively. Typically, each dye would have a fluorescence peak at different wavelengths (column 8, fourth paragraph). According to the embodiment in Figure 1c, two fluorescence colors could be detected by employing a second dichroic mirror, photomultiplier tube and associated lens, confocal pinhole and filter. The embodiment illustrated in Figure 1c might be expanded by one skilled in the art to detect more than two fluorescence colors by employing an additional dichroic mirror, photomultiplier tube and associated lens, confocal pinhole and filter for each additional fluorescence color to be detected (column 9, second paragraph). Note although the detection apparatus had been illustrated primarily herein with regard to the detection of marked targets, it would readily find application in other areas. For example, the detection

Art Unit: 1655

apparatus disclosed herein could be used in the fields of catalysis, DNA or protein gel scanning, and the like (column 16, last paragraph). This prior art meets the limitations of the claims.

Alternatively, this system can be used to detect the interaction between unlabeled substrate and two fluorescence-labeled targets. Such disclosure reasonably suggests the use of one or more fluorescence-labeled substrates. Therefore, and in the absence of convincing evidence to the contrary the claimed invention as whole is considered prima facie obvious, if not anticipated by the prior art of record.

Conclusion

11. No claim is allowed.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

Art Unit: 1655

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
July 28, 2000

B. L. Sisson
BRADLEY L. SISSON
PRIMARY EXAMINER
GROUP 1800-16550
7/31/00